JUL - 8 2005

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ABAXIS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051108

1. Applicant Information:

Date Prepared:	April 29, 2005
Name:	Abaxis, Inc.
Address:	3240 Whipple Road Union City, CA 94587
Contact Person:	Dennis M. Bleile, PhD
Phone Number:	(510) 675-6515
Fax Number:	(510) 441-6150

2. Device Information:

Classification	Class II
Trade Name:	Piccolo® Lactate Dehydrogenase Test System

Classification Name: Lactate Dehydrogenase Test system 862.1440

3. Identification of legally marketed device to which the submitter claims equivalence:

The following table identifies the legally marketed device to which Abaxis claims equivalence:

Predicate Device			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
Lactate Dehydrogenase Reagents on the Synchron LX20 Chemistry System	Beckman Coulter, Inc. (Brea, CA)	K011213	5/16/01

4. Description of the Device:

The Piccolo Basic Metabolic Panel Plus Reagent Disc (which contains the Piccolo Lactate Dehydrogenase Test System) is designed for heparinized plasma and serum, only. The disc meters the required quantity of sample and diluent, mixes

Summary of Safety and Effectiveness (continued)

the sample with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted samples mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer. Alternately, the disc may also be used with serum.

5. Statement of Intended Use:

The Piccolo Lactate Dehydrogenase Test System (presently contained on the Basic Metabolic Panel Plus Reagent Disc) used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of lactate dehydrogenase activity in heparinized plasma or serum in a clinical laboratory setting or point-of-care location.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

Table 1 outlines the technological characteristics of the Piccolo Lactate Dehydrogenase Test System in comparison to the legally marketed predicate device.

Table 1: Specification Comparison: Piccolo Lactate Dehydrogenase Test System

	Piccolo Point-of-Care Chemistry Analyzer	**Synchron LX20 Chemistry System**
Intended Use	Quantitative analysis of Lactate Dehydrogenase	Quantitative analysis of Lactate Dehydrogenase
Methodology	Enzymatic rate reaction	Enzymatic rate reaction
Sample Type	Heparinized plasma and serum	Heparinized plasma and serum
Sensitivity	50 U/L	5 U/L
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer Active ingredients: Lactate Nicotinamide adenine dicucleotide (NAD+) Diaphorase p-Iodonitrotetrazolium Violet (INT)	Liquid reagents Active ingredients: Lactate Nicotinamide adenine dicucleotide (NAD+)
Temperature of Reaction	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Calibration not required.
Assay Range	50 – 1,000 U/L	5 – 750 U/L (600 – 2,700 U/L ORDAC*)
Testing Environment	Professional use	Professional use

Summary of Safety and Effectiveness (continued)

Table 1: Specification Comparison: Piccolo Lactate Dehydrogenase Test System (continued)

	Piccolo Point-of-Care Chemistry Analyzer	Synchron LX20 Chemistry System
Sample Size	Approximately 100 µL	13 µL (3 µL ORDAC*)

7. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence.

Tables 2 summarize the results of clinical and non-clinical tests performed using the Piccolo Lactate Dehydrogenase Test System.

Linearity:

Table 2:
Summary of Linearity

	Lactate Dehydrogenase
Slope	1.012
Intercept	+0.253
Corr. Coefficient	0.998

Summary of Safety and Effectiveness (continued)

Precision:

Precision studies were designed to evaluate within-run and total precision of the Lactate Dehydrogenase Test System when run on the Piccolo Point-of-Care Chemistry Analyzer.

Table 3:
Within-Run and Total Precision for Lactate Dehydrogenase, Assayed on the Piccolo Point-of-Care Chemistry Analyzer

Analyte	Within-Run (n = 80)	Total (n = 80)
Lactate Dehydrogenase (U/L)		
Control Level 1		
Mean	87	87
SD	3.0	4.4
%CV	3.4	5.0
Control Level 2		
Mean	350	350
SD	3.8	7.0
%CV	1.1	2.0

Sample Type Comparison:

A study was conducted to examine and compare results for heparinized plasma and serum on the Piccolo® Point-of-Care Chemistry Analyzer.

Heparinized plasma and serum comparability were established for Lactate Dehydrogenase.

8. Conclusions

The clinical and non-clinical tests performed for Lactate Dehydrogenase, when run on the Piccolo Point-of-Care Chemistry Analyzer, demonstrate that the test system is as safe, effective and performs as well as the legally marketed device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 8 2005

Dennis M. Bleile Ph.D.
Director of Assay Performance &Compliance
Abaxis, Inc
3240 Whipple Road
Union City, CA 94587

Re: k051108
Trade/Device Name: Piccolo® Lactate Dehydrogenase Test
Regulation Number: 21 CFR 862.1440
Regulation Name: Lactate dehydrogenase test system
Regulatory Class: Class II
Product Code: CFJ
Dated: April 29, 2005
Received: May 2, 2005

Dear Dr. Bleile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051108

Device Name: Piccolo® Lactate Dehydrogenase Test System

Indications For Use:

The Piccolo Lactate Dehydrogenase Test System (presently contained on the Piccolo Basic Metabolic Panel Plus Disc) used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of lactate dehydrogenase activity in heparinized plasma or serum in a clinical laboratory setting or point-of-care location.

Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis and cirrhosis; cardiac diseases such as myocardial infarction; and tissue alterations of the heart, kidney, liver, and muscle.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051108